

Application No.: 10/652,100
Filing Date: August 28, 2003

REMARKS

The foregoing amendments and the following remarks are responsive to the November 1, 2007 Office Action (the "Office Action").

Prosecution History:

As noted in the Office Action, in Applicant's reply dated July 27, 2007, Applicant elected with traverse Claims 1-31 for further prosecution, cancelled claims 48-52, and added new Claims 53-56. By this present Amendment, Claims 32-40 are withdrawn from consideration as being drawn to a nonelected group, Claims 41-47 are canceled, and new Claims 57-65 are added, the new claims being directed to Group I as discussed in greater detail below. Therefore, Claims 1-31 and 53-65 are pending in the present application. Applicant reserves the right to pursue the cancelled and/or withdrawn claims at later date.

Claim Rejections:

While Applicant respectfully disagrees with the Examiner's rejections, to advance prosecution, Applicant has amended one or more claims to address the Examiner's comments. Applicant is not acquiescing to the rejections and reserves the right to pursue in a related application claims at least as broad as the amended claims prior to the amendments set forth herein. Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

Claim Rejections – 35 U.S.C. 102 - Claims 1-2, 4-5, 24, 26, 29, and 53-56:

The Examiner rejected Claims 1-2, 4-5, 24, 26, 29, and 53-56 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application No. 2003/0108587 ("Orgill"). Respectfully stated, Claims 1-2, 4-5, 24, 26, 29, and 53-56 are not anticipated by Orgill under 35 U.S.C. 102(e) because Orgill does not show every element of each claim arranged as in each claim. *See* MPEP §2131. Moreover, as discussed below Orgill also does not render obvious any of these claims.

Regarding Applicant's amended Claims 1 and 5, respectfully stated, Orgill does not disclose or suggest an appliance comprising a cover and an absorbable matrix, wherein the absorbable matrix comprises a first absorbable portion having a first rate of absorption of the

tissue into the first absorbable portion and a second absorbable portion having a second rate of absorption of the tissue into the second absorbable portion, the first rate of absorption being different than the second rate of absorption. At a minimum, on Applicant's understanding, Orgill does not disclose a matrix having two absorbable portions wherein each absorbable portion has a different rate of absorption. The Examiner's reference to Orgill paragraph [0034] at best indicates that Orgill teaches two biodegradable matrix layers; however, nowhere does Orgill teach or suggest absorbable portions with a first rate of absorption different from a second rate of absorption.

In addition, regarding Claim 5, Applicant submits that Orgill neither teaches nor suggests an absorbable matrix comprising "a plurality of layers with at least a lower layer and a higher layer, the lower layer having a higher rate of absorption than a rate of absorption of the higher layer." Moreover, Orgill does not disclose or suggest a segment of tubing that is embedded within the absorbable matrix. Orgill's Figure 8B may disclose the tube 120 passing through the dressing 115, but does not disclose or suggest whether the tube 120 terminates at the non-degradable sponge 110 or passes through the non-degradable sponge 110. More importantly, Figure 8B also does not disclose or suggest that the tube 120 passes through the first matrix layer 125a or the second matrix layer 125b. On Applicant's understanding, Orgill does not disclose or suggest anywhere in its disclosure or figure set that the tube 120 is embedded within the absorbable matrix, as is set forth in Claim 5.

Regarding Applicant's amended Claim 53, respectfully stated, Orgill does not disclose or suggest, inter alia, a first absorbable matrix and a second absorbable matrix, wherein the first absorbable matrix has a first rate of absorption of the tissue into the first absorbable matrix and the second absorbable matrix has a second rate of absorption of the tissue into the second absorbable matrix, and the first rate of absorption is different than the second rate of absorption. At a minimum, Applicant submits that Orgill does not disclose a first and second matrix each having a different rate of absorption.

Regarding Applicant's amended Claim 24, Applicant submits that Orgill does not disclose or suggest an appliance comprising a cover and a temperature monitor supported by the cover, wherein the temperature monitor is configured to provide a visual indication of the temperature of the wound such that a visual inspection of the appearance of the temperature

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monitor provides an indication of the temperature of the wound. In particular, Orgill does not disclose or suggest that the wound sensor array 170 (which the Office Action compares to the temperature monitor of Claim 24) provides a visual indication of the temperature of the wound such that a visual inspection of the appearance of the wound sensor array 170 provides an indication of the temperature of the wound. Moreover, the wound sensor array in Orgill is placed into the wound itself, and is not supported by the dressing 115 of Orgill.

Applicant notes that the Examiner may wish to rely on a combination of Orgill with Allen, as applied to Claims 27 and 28, to reject amended Claim 24. As discussed below with respect to Claims 27 and 28, Applicant submits that a combination of Orgill with Allen to make an obviousness rejection would be improper.

Regarding Claims 2, 4, 26, 29, and 54-56 respectfully stated, these claims are not anticipated or suggested by Orgill for at least the same reasons as for the claim or claims from which they depend, and also because they each recite further patentable distinctions. Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 1-2, 4-5, 24, 26, 29, and 53-56 in view of the amendments and clarifications listed above.

Claim Rejections – 35 U.S.C. 102 - Claims 6, 8-11, 14, and 16-21:

The Examiner rejected Claims 6, 8-11, 14, and 16-21 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application No. 2003/0050594 (“Zamierowski”). Respectfully stated, Claims 6, 8-11, 14, and 16-21 are not anticipated by Zamierowski under 35 U.S.C. 102(e) because Zamierowski does not show every element of each claim arranged as in each claim. *See* MPEP §2131. Moreover, as discussed below Zamierowski also does not render obvious any of these claims.

Regarding Applicant’s amended Claim 6, respectfully stated, Zamierowski does not disclose or suggest an appliance for monitoring pressure during treatment of any body part of a patient comprising a cover having means for monitoring the level of pressure at the site of the body part being treated. Applicant submits that Claim 6 as amended recites a means-plus-function limitation, and as such is construed to cover the corresponding structure disclosed in the

specification and equivalents thereof. One example of the corresponding structure can be found in the description of protrusions shown in Figure 5a of Applicant's specification.

By contrast, Zamierowski's paragraph 59 states that, [i]n operation, evacuating the dressing 202 causes portions of it to shrink, compress and collapse under the pressure gradient, thus providing a visual indication of its performance." Zamierowski's paragraph 59 does not disclose or suggest that the dressing 202 monitors the *level of pressure* at the site of the body part being treated – paragraph 59 merely discloses that the *performance* of the dressing 202 can be visually indicated. Further, the means for monitoring the level of pressure as recited in Claim 6 provides for a separate structure apart from the cover of the appliance of Claim 6. It is the *means for monitoring the level of pressure*, as opposed to the *cover*, that allows the level of pressure at the site of the body part being treated to be monitored. In contrast, the Office Action contends that it is the cover or dressing of Zamierowski that enables monitoring. In some configurations, the means for monitoring the level of pressure of Claim 6 can be integrated into the cover, but, nonetheless, it is still the means for monitoring the level of pressure that provides such monitoring.

Regarding Applicant's amended Claim 14, although Claim 14 does not include a means-plus-function limitation as in Claim 6, it is still allowable over Zamierowski for similar reasons. Zamierowski does not disclose or suggest an appliance comprising a cover and a pressure monitor supported by the cover, wherein the pressure monitor is configured to provide a visual indication of the *level of reduced pressure* between the cover and the wound such that a visual inspection of the appearance of the pressure monitor provides an indication of the *level of reduced pressure* between the cover and the wound. Similar to Claim 6, Claim 14 makes clear that it is the visual inspection of the *pressure monitor*, as opposed to the *cover*, that provides the visual indication of the level of reduced pressure between the cover and the wound.

Regarding Claims 8-11 and 16-21, respectfully stated, these claims are not anticipated or suggested by Zamierowski for at least the same reasons as for the claim or claims from which they depend, and also because they each recite further patentable distinctions.

Accordingly, Applicant respectfully requests that Examiner to reconsider and withdraw the rejection of Claims 6, 8-11, 14, and 16-21 in view of the amendments and clarifications listed above. In particular, regarding Claim 17, Zamierowski's paragraph 53 states that the feature 106

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is a collector assembly. Accordingly, Zamierowski does not disclose or suggest the appliance of Claim 14, further comprising an *absorbable matrix* adapted to encourage growth of tissue in the area of the wound into the matrix.

Claim Rejections – 35 U.S.C. 103

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.* (“Examination Guidelines”), which were published in the Federal Register Vol. 72, No. 195 (Docket PTO-P-2007-0031) on October 10, 2007, clarify the Supreme Court’s decision on *KSR Int’l. v. Teleflex, Inc.* with regard to the issue of obviousness under 35 U.S.C. §103(a) in relation to prior art. *KSR Int’l. v. Teleflex, Inc.*, No 04-1350 (U.S. Apr. 30, 2007). Applicant submits that the outstanding Office Action fails to satisfy the Examiner’s burden in establishing an obviousness rejection.

Under the Examination Guidelines, and as reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in *Graham v. John Deere Co.* Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

The Examination Guidelines confirms the role of Patent Office personnel as factfinders:

When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness.

72 Fed. Reg. 57527 (Oct. 10, 2007).

The Examination Guidelines further provide that “[o]nce the *Graham* factual inquiries are resolved, Office personnel must determine whether the claimed invention would have been obvious to one of ordinary skill in the art.” *Id.* “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some

rational underpinning to support the legal conclusion of obviousness.” *Id.* at 57528-57529 (internal citations omitted). Under the Examination Guidelines, a rejection must offer specific support for the following rationales Examiners may use to show obviousness:

- (A) Combining prior art elements according to known methods to yield predictable results;
- (B) Simple substitution of one known element for another to obtain predictable results;
- (C) Use of known technique to improve similar devices (methods, or products) in the same way;
- (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;
- (E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;
- (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;
- (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Id. at 57529.

For example, in order to reject a claim on rationale (G) above, Office personnel must first resolve the *Graham* factual inquiries, and then must articulate the following:

- (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings;
- (2) a finding that there was reasonable expectation of success; and
- (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

Id. at 57534. The rationale to support a conclusion that the claim would have been obvious is that “a person of ordinary skill in the art would have been motivated to combine the prior art to achieve the claimed invention and that there would have been a reasonable expectation of success.” *Id.* If any of these findings cannot be made, then this rationale cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. *Id.* An explicit suggestion to combine the prior art is not necessary, but “[i]n such situations, the

proper question is whether the ordinary artisan possess knowledge and skills rendering him capable of combining the prior art references.” *Id.* (internal citations omitted).

The November 1, 2007 Office Action fails to set forth the level of ordinary skill in the pertinent art, or who qualifies as one of ordinary skill in the field. Applicant submits that without such a finding, the Examiner’s combinations are improper, as the Examiner has not established that the references proposed by the combinations would be known to one of ordinary skill in the art, nor that one of ordinary skill would have the requisite knowledge and ability to make the desired combinations. Moreover, the Examiner has failed articulate specific rationales for the proposed combinations of references, and has failed to provide explicit explanations supporting the obviousness rejections. Rather, the Examiner makes merely conclusory statements regarding the combinability of the cited prior art references, without identifying the knowledge one skilled in the art would possess, what modifications the skilled person would need to make to combine the prior art references, and whether that skilled person would have a reasonable expectation of success. Accordingly, Applicant submits that the Examiner’s obviousness rejections are improper. More specific details relating to these missing inquiries and missing articulated findings are discussed below with respect to particular rejections, along with Applicant’s reasoned statements explaining why Applicant’s claims are nonobvious over the cited art.

Claims 3 and 25:

The Examiner rejected Claims 3 and 25 under 35 U.S.C. 103(a) as being unpatentable over Orgill in view of U.S. Patent Application No. 2002/0065494 (“Lockwood”). Respectfully stated, Claims 3 and 25 are not unpatentable over Orgill in view of Lockwood because Lockwood does not overcome Orgill’s failure to disclose or suggest all of the limitations set forth in the claims from which Claims 3 and 25 depend (described above), and, because the additional patentable limitations set forth in Claims 3 and 25 and the limitations of the claims from which they depend would not have been obvious to one of ordinary skill in the art in view of Orgill and Lockwood at the time of the inventions.

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Claims 27 and 28:

The Examiner rejected Claims 27 and 28 under 35 U.S.C. 103(a) as being unpatentable over Orgill in view of U.S. Patent Application No. 2003/0014025 ("Allen"). Applicant asserts that one skilled in the art would not have combined Orgill with Allen, and that the Examiner has not articulated a proper rationale why one skilled in the art would have combined the prior art elements in the manner claimed by the Applicant.

Orgill and Allen Are Not Properly Combinable

Applicant submits that one skilled in the art would not look to Allen to modify an apparatus for application of micro-mechanical forces to promote tissue growth and wound healing in mammals as in Orgill (*see* Orgill, ¶ [0006]), because Allen is directed to wearable and absorbent articles having a fever indicator. *See* Allen, ¶ [0013]. The Examiner has made no factual findings that one skilled in the art of reduced pressure wound therapy would have knowledge of the Allen devices and methods relating to wearable and absorbent articles having a fever indicator, and Applicant submits that it would be beyond the knowledge of one skilled in the relevant art (reduced pressure wound therapy) to utilize the teachings of Allen and modify them to produce Applicant's claimed invention with any reasonable expectation of success.

For example, with regard to Claim 24 (from which Claims 27 and 28 depend), Orgill teaches an occlusive dressing that covers, *inter alia*, a wound and a biodegradable matrix (*see* Orgill, ¶ [0033]-[0034]), and one skilled in the art would not understand from Allen or his or her own knowledge how to modify Orgill in an operable way to provide an appliance for administering a reduced pressure treatment to a wound comprising, *inter alia*, a cover and a temperature monitor *supported* by the cover wherein the temperature monitor is configured to provide a visual indication of the temperature of the wound such that the visual inspection of the appearance of the temperature monitor provides an indication of the temperature of the wound. The reduced pressure wound therapy environment is much different from the wearable and absorbent article environment, and it goes beyond a mere combination of known elements to produce the claimed invention. Moreover, for the reasons stated above, one skilled in the art would similarly not understand from Allen (or his or her own knowledge) how to modify the occlusive dressing in Orgill to *support* such a wearable or absorbent article in an operable way.

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With regard to Claim 27, for the reasons stated above, one skilled in the art would not understand from Allen or his or her own knowledge how to modify Orgill in an operable way to provide a reduced pressure treatment appliance comprising, inter alia, a cover, a temperature monitor comprising one or more layers of temperature-sensitive material located between the cover and the wound, wherein one of the one or more layers of temperature-sensitive material is configured to change from one color to another color or from one shade to another shade of the same color as the temperature of the wound changes. Similarly, with regard to Claim 28, one skilled in the art would not understand from Allen or his or her own knowledge how to modify Orgill in an operable way to provide the reduced pressure treatment appliance of Claim 28 wherein the temperature-sensitive material is attached to a surface of the cover so that the cover and the temperature-sensitive material comprise a single integrated unit. Again, the reduced pressure wound therapy environment is much different from the wearable and absorbent article environment, and it goes beyond a mere combination of known elements to produce the claimed invention.

Applicant submits that one skilled in the art would not have any reasonable expectation of success in making the proposed combination in view of the fact that Allen is in a different field of endeavor than Orgill, and the extensive modifications that would need to be made in order for the proposed combination to be operable. For these reasons, Applicant submits that the Examiner's obviousness rejection over Orgill and Allen is improper, and the rejections of the claims based on this combination be withdrawn.

Claim 28 Recites Additional Features Not Taught or Suggested by the Cited Art

Amended Claim 28 recites, inter alia, a reduced pressure treatment appliance comprising a cover, a temperature monitor comprising one or more layers of temperature-sensitive material located between the cover and the wound, wherein the temperature-sensitive material is attached to a surface of the cover so that the cover and the temperature-sensitive material comprise a single integrated unit. In addition to other features, the combination of Orgill in view of Allen does not disclose, teach or suggest an appliance wherein the temperature-sensitive material is attached to a surface of the cover so that the cover and the temperature-sensitive material

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comprise a single integrated unit. Accordingly, for this additional reason, Applicant submits that Claim 28 is allowable over the cited references.

Claims 30 and 31:

The Examiner rejected Claims 30 and 31 under 35 U.S.C. 103(a) as being unpatentable over Orgill in view of U.S. Patent No. 7,004,915 ("Boynton"). Respectfully stated, Claims 30 and 31 are not unpatentable over Orgill in view of Boynton because Boynton does not overcome Orgill's failure to disclose or suggest all of the limitations set forth in the claims from which Claims 30 and 31 depend (described above), and because the additional patentable limitations set forth in Claims 30 and 31 and the limitations of the claims from which they depend would not have been obvious to one of ordinary skill in the art in view of Orgill and Boynton at the time of the inventions. In particular, regarding Claim 30, on Applicant's understanding, Boynton discloses an alarm that may be automatically activated if an air leak is detected at the wound site (see column 7, lines 30-31). However, neither Orgill nor Boynton disclose or suggest an alarm device that provides an alarm signal when the *temperature* measured by any temperature sensing device exceeds or is lower than a predetermined value.

Claims 7, 12-13, 15, and 22-23:

The Examiner rejected Claims 7, 12-13, 15, and 22-23 under 35 U.S.C. 103(a) as being unpatentable over Zamierowski in view of Lockwood. Respectfully stated, Claims 7, 12-13, 15, and 22-23 are not unpatentable over Zamierowski in view of Lockwood because Lockwood does not overcome Zamierowski's failure to disclose or suggest all of the limitations set forth in the claims from which Claims 7, 12-13, 15, and 22-23 depend (described above), and because the additional patentable limitations set forth in Claims 7, 12-13, 15, and 22-23 and the limitations of the claims from they depend would not have been obvious to one of ordinary skill in the art in view of Zamierowski and Lockwood at the time of the inventions.

New Claims Have Been Added:

New Claims 57-65 have been added. These claims are fully supported by the application as filed such that no new matter has been introduced by this Amendment. The newly added

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claims, which are all dependent claims, read on the elected invention - Group I. Regarding the art references cited in the Office Action, Applicant submits that the Claims 57-65 are not anticipated or suggested by, or unpatentable over, the cited references for at least the same reasons as for the claim or claims from which they depend, and also because they each recite further patentable distinctions.

Withdrawn Claims Have Been Amended:

Applicant draws Examiner's attention to the fact that withdrawn Claims 32, 35, and 38 have been amended herein. Applicant has amended the above-listed claims in a manner that is consistent with the amendments to the elected claims so that, if the elected claims are allowed, the withdrawn claims can be reinstated and overcome the rejections stated in the Office Action.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/075,020 BLSKY.013A	ENCLOSURE-BASED REDUCED PRESSURE TREATMENT SYSTEM	03-08-2005

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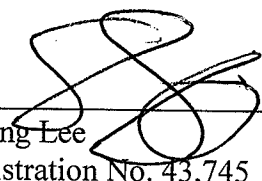
11/095,859 BLSKY.014A	ADJUSTABLE OVERLAY REDUCED PRESSURE WOUND TREATMENT SYSTEM	03-31-2005
11/098,203 BLSKY.015A	REDUCED PRESSURE WOUND CUPPING TREATMENT SYSTEM	04-04-2005
11/132,549 BLSKY.016A	HYPOBARIC CHAMBER TREATMENT SYSTEM	05-19-2005
11/064,813 BLSKY.017A	FLEXIBLE REDUCED PRESSURE TREATMENT APPLIANCE	02-24-2005
11/098,265 BLSKY.017CP1	FLEXIBLE REDUCED PRESSURE TREATMENT APPLIANCE	04-04-2005
11/491,578 BLSKY.018A	NEGATIVE PRESSURE PROTECTION SYSTEM	07-24-2006

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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